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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/452,843	05/30/95	SETTE	A 014137-00802

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EXAMINER	
DIBRINO, M	
ART UNIT	**PAPER NUMBER**
1644	24

DATE MAILED: 11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/452,843	Sette et al
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Aug 20, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *67-165* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *67-165* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. Applicant's amendment filed 08/20/99 has necessitated the following new restriction.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 67-75, 78-85, 89-116, 120-139, 142-154 and 157-165, drawn to a method for making a peptide wherein the preparing, providing or obtaining step comprises providing an amino acid sequence for said peptide, classified in Class 514, subclasses 15 and 16.

II. Claims 76-77, 86-88, 117-119, 140-141 and 155-156, drawn to a method for making a peptide using a nucleic acid that encodes said peptide, classified in Class 435, subclass 69.1.

4. Inventions I and II are different methods.

These inventions require different ingredients and process steps to accomplish the use of making a peptide. For example, Invention I uses peptides, whereas Invention II uses nucleic acids that express said peptides.

Therefore they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-II is not required for any other group from Groups I-II and Groups I-II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed Invention: a method of inducing an immune response with a peptide/pharmaceutical composition, thereof wherein the peptide sequence is one of the peptides disclosed in the specification and is encompassed by the elected motif amino acid at the elected motif position. Applicant is required to elect a specific species of peptide and motif, for example, SEQ ID NO: 2 and the motif P at Position 2 and L at the carboxy terminal position.

These peptides are functionally and structurally distinct.

7. In addition, this application contains claims directed to the following patentably distinct species of the claimed invention:

A) a peptide of 8 amino acid residues (claims 67-101, 103-132, 134-146, 148-164)
B) a peptide of 9 amino acid residues (claims 67-101, 103-132, 134-146, 148-164)
C) a peptide of 10 amino acid residues (claims 67-101, 103-132, 134-146, 148-164)
D) a peptide of 11 amino acid residues (claims 67-101, 103-132, 134-146, 148-164)

E) a peptide of more than 11 amino acid residues (claims 102, 133, 147, 165).

These peptides are distinct because they have different lengths and hence, different structures and different physico-chemical properties.

Applicant is required to elect a specific species of peptide having a specific length, i.e., one of A-E above.

8. Where applicable, Applicant is further required to elect one ultimately disclosed species of antigen of interest which is:

A) a cancer-associated antigen **or**
B) a pathogenic agent.

If a cancer-associated antigen is elected, Applicant is further required to elect one of the patentably distinct species of cancer antigen disclosed, for example MAGE 2 or p53.

If a pathogenic agent is elected, Applicant is further required to elect one of the patentably distinct species disclosed, for example, HBV or HCV.

These species are distinct because they have different structures and physico-chemical properties and cause different diseases.

9. Where applicable, Applicant is further required to elect a single disclosed species of method wherein the testing step occurs in vivo or in vitro, the determining whether the peptide is immunogenic step occurs in vivo or in vitro and the contacting step occurs in vivo or in vitro.

These species are distinct because the in vitro and in vivo methods require different ingredients, process steps and endpoints. For example, the contacting of CTL with the complex or the testing step or the determining step in vitro requires provision of, culture of and testing of CTL in vitro, whereas the contacting of CTL with the complex or the testing step or the determining step in vivo only requires administration of the peptide or the peptide/HLA complex.

10. Where applicable, Applicant is further required to elect a single disclosed species of method wherein the identifying a peptide that an IC50 of a specified value step or the determining binding affinity step involves one of the HLA molecules recited in claims 70 and 71.

These species are distinct because they use different HLA molecules which have distinct functional and structural properties.

11. Where applicable, Applicant is further required to elect a single disclosed species of method wherein the contacting step or the testing step comprises contacting a CTL restricted to HLA-B0701, -B1401, -B3501, -B3503, -B5101, -B5301, B5401 or -Cw6 with a complex of a peptide and one of HLA-B0701, -B1401, -B3501, -B3503, -B5101, -B5301, B5401 or -Cw6.

These species are distinct because they use different HLA molecules which have distinct functional and structural properties.

12. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
November 19, 1999

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600